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MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS, FL 33410

EXAMINER	
CHERNYSHEV, OLGA N	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/991,799
Filing Date: November 23, 2001
Appellant(s): JACKOWSKI ET AL.

Ferris H. Lander
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 17, 2007 appealing from the Office action mailed March 16, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

US Application 09/991,799, "Plasma protease C1 inhibitor biopolymer marker indicative of Alzheimer's disease", appeal brief filed 01/2007;

US Application 09/994,909, "Complement C3 precursor biopolymer markers related to Alzheimer's disease", appeal brief filed 01/2007;

US Application 09/993,344, "Glycoprotein and apolipoprotein biopolymer markers predictive of Alzheimer's disease", appeal brief filed 01/2007.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility or a well established utility.

Claim 1 is drawn to two biopolymer marker peptides consisting of SEQ ID NO: 1 and SEQ ID NO: 4 which evidence a link to Type II diabetes. The instant specification presents the following definition of the term "biopolymer marker": "the term "biopolymer markers indicative or predictive of a disease state" is interpreted to mean that a biopolymer marker which is strongly present in a normal individual, but is down-regulated in disease is predictive of said disease; while alternatively, a biopolymer marker which is strongly present in a disease state, but is down-regulated in normal individuals, is indicative of said disease state. Biopolymer markers which are present in both disease and normal states are indicative/predictive based upon their relative strengths in disease vs. normal, along with the observation regarding when their signal strengthens/weakens relative to disease manifestation or progression" (p. 11).

At pp. 29-31, the specification explains the significance of identifying a plurality of disease specific marker sequences associated with Syndrome-X: "Syndrome-X is a multifunctional syndrome, which occurs frequently in the general population. [..]This disease is characterized by the clustering of insulin resistance and hyperinsulinemia, and is often associated with dislipidemia [...],hypertension, abdominal (visceral) obesity, glucose intolerance or noninsulin-dependent diabetes mellitus and an increased risk of cardiovascular events. [...] A patient who begins the Syndrome X continuum risks spiraling into a maze of increasingly deadly diseases. The next stages of the Syndrome X continuum lead to overt diabetes, kidney failure, and heart failure, with the possibility of stroke and heart attack at any time. Syndrome X is a dangerous continuum, and preventive medicine is the best defense". The specification further contemplates obtaining samples from a patient and monitoring specific biopolymer markers to assess a Syndrome X disease state as well as to develop methods and means to treat Syndrome X (pp. 32-35). Type II diabetes is described within the context of the Syndrome X diseases (p. 30).

The specification discloses a protocol of how peptides of SEQ ID NO: 1 and SEQ ID NO: 4 were isolated at pp. 25-26 and 40-46. Specifically, protein content of a sample obtained from a subject was (1) separated by gel electrophoresis, (2) a band of interest was selected based on visual observation of difference of darkness/lightness of the band as compared to other bands, excised and purified from the gel, (3) protein content of the band was subjected to "[T]ryptic digestion of each band" (p. 25), and (4) the fragments, which were the results of artificial proteolytic digestion of the proteins within the band, were identified by means of mass spectrography. At pp. 46-47, it is stated that as a result of these procedures, six fragments of fibronectin precursors, two of them are the currently claimed peptides of SEQ ID NO: 1 and

SEQ ID NO: 4, "related to Type II diabetes were found". It is not disclosed if the fragments were present, not present or present at different levels in samples identified as obtained from Type II diabetes patients.

A specification can meet the legal requirements of utility and enablement for a new peptide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new peptide, or a well-established utility for the claimed peptide would be readily apparent to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed peptide is expressed in colon cancer and not expressed in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the polynucleotide. The claimed peptide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. Alternatively, a hypothetical specification could disclose that a claimed peptide is expressed at specific altered levels in colon cancer as compared to healthy colon tissue. One skilled in the art would immediately recognize that the peptide in hypothetical example would be useful as a colon cancer marker. However, such is not the fact pattern here.

The instant specification discloses finding of six artificially produced fragments of a larger naturally occurring molecule, and asserts their relation to Type II diabetes. First, there is no evidence of record that these peptides (biopolymer markers of SEQ ID NO: 1 and SEQ ID NO: 4) are naturally occurring fragments, which are the results of a pathological cleavage of a larger molecule during Type II diabetes, for example, so that they can be easily detected in a sample as a diagnostic measure. In order to obtain the peptides of SEQ ID NO: 1 and SEQ ID

NO: 4, protein content of a sample must be first cleaved by trypsin, which is a proteolytic digestive enzyme. The specification provides no evidence or sound scientific reasoning to support a conclusion that enzymatic digestion of the serum protein samples by trypsin would predictably lead to the same production of the fragments of SEQ ID NO: 1 and SEQ ID NO: 4.

Second, the instant specification fails to explain the relationship between peptides of SEQ ID NO: 1 and SEQ ID NO: 4 and Type II diabetes. It is stated on page 47 that, "Figures 1 and 3 are photographs of a gel which is indicative of the presence/absence of the marker in disease vs. control and, in cases where the marker is always present, the relative strength, e.g. the up or down regulation of the marker relative to categorization of disease state is deduced". While it is not necessary that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding the following questions must be answered. Is it "the up or down regulation of the marker relative to categorization of disease state"? Or is "the presence/absence" of the peptide of SEQ ID NO: 1 or SEQ ID NO: 4 indicative of a disease?

Further, the instant specification, as originally filed, fails to disclose any specific information regarding the data presented in Figures 1 and 3, such as, description of the samples, their type, size, representative number, which constitutes a major critical issue when it comes to evaluation of experimental data. Without this important information, the worker of skill in the art would have to engage in significant further research to experiment, discover and define "the link" between peptides of SEQ ID NO: 1 and SEQ ID NO: 4 and Type II diabetes.

Applicant's invention is predicated on the finding that serum samples obtained from patients with Type II diabetes, such samples being processed/digested by enzymes, contain or

lack multiple fragments of a fibronectin precursor molecule. Applicant further extrapolates this result into an assertion that peptides of SEQ ID NO: 1 and/or SEQ ID NO: 4 can be used as a biopolymer marker, "which evidences a link to Type II diabetes". Accordingly, it would appear that Applicant provides a single finding (the finding), and then presents an invitation to experiment and determine if peptides of SEQ ID NO: 1 and SQE ID NO: 4 could be used as biopolymer markers for Type II diabetes. Such experimentation would include determination if peptides of SEQ ID NO: 1 and/or SEQ ID NO: 4 are absent or present or present at particular levels in a specific tissue or body fluid sample of persons suffering from Type II diabetes or who are at risk of developing Type II diabetes *versus* other forms of diabetes and normal individuals.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

To employ fragments of fibronectin precursor molecule, the claimed peptides of SEQ ID NO: 1 and SEQ ID NO: 4, as a diagnostic tool, which evidences a particular meaningful link to Type II diabetes, would clearly be using them as an object of further research, which has been

determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the clamed peptides in their currently available form, then the instant invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(10) Response to Argument

A. *Claim Rejections - 35 USC § 101*

1. At p. 10 of the Brief, Appellant submits that the instant specification discloses "an invention that is useful to the public as disclosed in its current form, rather than at some future date after further research, as peptide markers linked to Type II diabetes". Appellant further reviews the case law pertained to the utility under 35 U.S.C. 101, and the appropriate sections of MPEP (pp. 10-12, 14-15 and 17-19 of the Brief). Appellant's review of the issue of utility, the case law that has been cited and the holding that is found in that case law is not disputed. The

only point of disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility.

At pp. 10-11 of the Brief, Appellant argues that "the Examiner should presume that the claimed peptides (SEQ ID NOS: 1 and 4) are useful as markers for Type II diabetes based upon Applicants' showing in Figures 1 and 3 that the peptides are linked to Type II diabetes by their differential expression in Type II diabetes patients as compared to healthy control patients". The Examiner disagrees.

The currently claimed peptides of SEQ ID NO: 1 and SEQ ID NO: 4 are, respectively, a fifteen amino acid long and a seventeen amino acid long (see Sequence Listing of 04/23/2002) fragments of a longer full-length naturally occurring protein molecule. The evidence that peptides of SEQ ID NO: 1 and SEQ ID NO: 4 are not presented in Figure 1or in Figure 3 can be found within the Figure 1 and Figure 3 as well as within the text of the instant specification, as filed.

Specifically, "Figure 1 is a photograph of a tricine gel DEAE 1 (Elution) comparing normal human specimen versus Type II diabetes", see p. 37 of the instant specification. The gel electrophoresis technique is one of the old staple tools in molecular biology, which allows identification of molecules by the band pattern according to their molecular weight. It is clear that the bands presented in Figure 1 cannot possibly represent peptides of SEQ ID NO: 1 or SEQ ID NO: 4, which are only fifteen-seventeen amino acids long and have a molecular weight of not more than 2000 dalton (see p. 46 of the instant specification), and, therefore, cannot be seen within a gel where "high molecular weight standards" (see also the box at Fig. 3) were used. Further, the instant specification specifically states that "[I]n the instantly disclosed invention,

we deal with proteins having a molecular weight of about 20 kD or more. In general, proteins of greater than 20 kD can reliably be fragmented by trypsin or other enzymes. [...] Proteins differ from peptides in that they cannot be effectively resolved by time flight MS and they are too large (>3kD) to be effectively fragmented by collision with gases. [...] Once the proteins have been resolved and visualized with stains the proteins that differ between disease states can then be excised from the gel and the protein purified in the 1-D gel band or 2-D gel spot can be cleaved into fragments less that 3kD by proteolytic enzymes" (pp. 38-39). Moreover, Appellant's own explanation of the technique used to isolate the instant claimed peptides confirms that "proteins, as collected from a serum sample, are too large to be effectively resolved by mass spectrometry and thus, are often first subjected to separation by polyacrylamide gel electrophoresis. Upon electrophoresis, the proteins contained in the sample separate into bands in specific areas of the gel according to weight and charge. The separate protein bands which are observed and deemed to be different between two comparable states (for example, disease vs. normal state) are excised from the gel and subjected to further fragmentation by enzymes", emphasis added (p. 11 of the Brief).

Thus, Figures 1 and 3 relate to stage III of the protocol as presented at p. 12 of the Brief, where the raw mixture of proteins from the samples collected from four patients with Type II diabetes, four normal control and one normal control of pooled serum, was separated according to the molecular weight and charge within the gel. The instant claimed peptides of SEQ ID NO: 1 and SEQ ID NO: 4 are present within the band only in so far as they are part of the structure of the larger naturally occurring molecule of a protein present within the bands. As stated at p. 12 of the Brief, only during artificial digestion ("fragmentation", see stage V at p. 12 of the Brief),

fragments of SEQ ID NO: 1 and SQE ID NO: 4 were found to be "differentially expressed" between age-matched control subjects and patients with Type II diabetes.

The instant specification discloses peptides of SEQ D NO: 1 and SEQ ID NO: 4 and asserts their practical utility as "biopolymer marker[s] which evidence a link to Type II diabetes". However, the instant specification fails to teach what constitutes "a link to Type II diabetes" and how to use the instant claimed peptides to make "the evidence" assessment.

The current law requires that utility must be disclosed to satisfy the section 112 enablement requirement. "[T]he how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. §101 that the specification disclose as a matter of fact a practical utility for the invention." *In re Cortright*, 165 F.3d 1353, 1356 [49 USPQ2d 1464] (Fed. Cir. 1999), *quoting In re Ziegler*, 992 F.2d 1197, 1200 [26 USPQ2d 1600] (Fed. Cir. 1993); *see also In re Schoenwald*, 964 F.2d 1122, 1124 [22 USPQ2d 1671] (Fed. Cir. 1992) (stating that utility must be disclosed to satisfy the section 112 enablement requirement). In explaining what constitutes a sufficient showing of utility in the context of the enablement requirement, this court has stated that an applicant's failure to disclose how to use an invention may support a rejection under either section 112, paragraph 1 for lack of enablement, or "section 101 for lack of utility 'when there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.'" *Cortright*, 165 F.3d at 1356, *quoting Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762 [221 USPQ 473] (Fed. Cir. 1984).

In the instant case, Appellant claims peptides asserted to be useful as Type II diabetes markers; however, there is no disclosure of the significance of finding of peptide of SEQ ID NO: 1 and/or SEQ ID NO: 4 in a sample obtained from a patient. For example, if a peptide of SEQ ID

NO: 1 was found in a sample, what would that mean to the skilled practitioner? Is it a diagnosis of the absence or presence of Type II diabetes, or is it evidence that the patient has a link to Type II diabetes, and if such, what does this link represent? The instant specification does not teach finding of the instant claimed peptides of SEQ ID NO: 1 and/or SEQ ID NO: 4 in any sample obtained from a patient with Type II diabetes, the only information disclosed is limited to purification of a larger protein, which has a structural identity of fifteen common amino acids with the instant claimed peptides. There is no disclosure that the fibronectin precursor molecule itself is differentially expressed (present/absent, expressed at altered levels etc.), and there is also no evidence of record that these peptides of SEQ ID NO: 1 and SEQ ID NO: 4 are naturally occurring fragments that are specifically associated with Type II diabetes pathology and, therefore, can be easily identified or measured within a biological sample. For that reason, the currently available information, which is limited only to (1) the structure of the peptides and (2) the explanation of how the peptides were produced and purified by means of artificial enzymatic fragmentation, clearly does not constitute a sufficient showing of utility of the claimed peptides as markers for Type II diabetes.

Appellant argues that "an applicant is not required to provide evidence of an asserted utility as a matter of statistical certainty" and that "providing a point of reference that is critical for diagnosis with respect to differential expression of the claimed peptides is not necessary to establish credibility of the asserted use for the claimed peptides as markers for Type II diabetes" (p. 14 of the Brief). However, in the instant case, the only information available in the instant specification, as filed, is limited to disclosure of the amino acid sequence of the peptides of SEQ ID NO: 1 and SEQ ID NO: 4 a vague indication that the peptide "is present/absent in disease vs.

control" (p. 46 of the specification), with no further explanation or guidance for a skilled practitioner as to what represents the "link to Type II diabetes".

It is important to point out that the photograph of the gel as presented in Figures 1 and 3 did not allow the Examiner to distinguish between the bands marked as Type II diabetes and "Normal", as there appears to be no visible difference in the presence or absence of any of the specific band type. The instant specification fails to specifically point out if the peptides of SEQ ID NO: 1 and/or SEQ ID NO: 4 were present or absent in samples related to Type II diabetes (see description of figures at p. 46-47). The Declaration of Ferris Landis under 37 CFR 1.132 filed on January 17, 2007, states that the peptides of SEQ ID NO: 1 was not found in sera obtained from Type II diabetes patients, section 2(a); however, in Response filed on May 16, 2005, Appellant specifically clarified that the "the claims no longer recite that the claimed biopolymer markers are diagnostic for Type II diabetes" (top at p. 29).

The Examiner disagrees that "[t]he identification of the claimed peptides showing differential expression in Type II diabetes relative to healthy control patients puts a researcher one step closer to understanding the pathogenesis of Type II diabetes and, thus, also one step closer to improved diagnosis and treatment of Type II diabetes" (p. 16 of the Brief). The Examiner maintains that the instant specification describes the structure of two peptides, SEQ ID NO: 1 and SEQ ID NO: 4, but discloses no utilities based on the detection of these peptides in a sample. The instant specification presents no factual evidence or sound scientific reasoning to support a conclusion that peptides of SEQ ID NO: 1 and/or SEQ ID NO: 4 are specifically associated with pathogenesis of Type II diabetes, or involved in a particular physiological process leading to Type II diabetes, or even present/absent in Type II diabetes samples, as the

only data available for determination is limited to the expression of fibronction precursor molecule.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. *See In re Fisher,* 2005 WL 2139421 (Sept. 7, 2005). The *Fisher* court interpreted *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility" 2005 WL 2139421, at *4. The *Fisher* court held that § 101 requires a utility that is both substantial and specific. *Id.* At *5. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Id.*

The court held that a specific utility is "a use which is not so vague as to be meaningless." *Id.* In other words, "in addition to providing a 'substantial' utility, an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.*

Just as in *Fisher* case where the Board reasoned that use of the claimed ESTs for the identification of polymorphisms is not a specific and substantial utility because "[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage," (*Id.*, slip op. at 15), in the instant case, the detection of the peptide of SEQ ID NO: 1 and/or SEQ ID NO: 4 in a sample obtained from a subject provides no meaningful information with respect to diagnosis or treatment of Type II diabetes, as asserted by Appellant.

Appellant submits that unlike to the invention of Fisher, "the claimed peptides are disclosed as markers of a specific disease condition, Type II diabetes" (middle at p. 19 of the Brief). However, the evidence of record is inadequate to support such conclusion because there is no evidence of record to show that peptides of SEQ ID NO: 1 and/or SEQ ID NO: 4 are markers of Type II diabetes. It is noted that Appellant uses terms "marker which evidences a link to Type II diabetes" and "biopolymer marker of Type II diabetes" interchangeably. However, since the instant specification fails to particularly point out what constitutes "a link to Type II diabetes", the presence of this limitation in the claim almost raises to the level of indefinite language for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. At pp. 20-21 of the Brief, Appellant argues that "it is improper for Office personnel to merely question operability [of the invention]". Appellant submits that "the Examiner requires Applicant to provide complete characterization of the claimed peptides, including data indicating what amount of the claimed peptides is diagnostic of Type II diabetes, to establish a utility for the claimed peptides". Appellant cites *Cortright* and states "that there is no per se requirement for clinical evidence to establish the utility of any invention". However, Appellant mischaracterizes the Examiner's position. The Examiner has never required to provide a complete characterization of the claimed peptide, or to present clinical evidence to establish the utility of the claimed peptide as a marker of (or an evidencer of a link to) Type II diabetes. The only question with respect to the use of the instant claimed peptides of SEQ ID NO: 1 and SEQ ID NO: 4 that was asked by the Examiner was, what is the significance of finding this peptide in a sample? Since the instant specification, as originally filed, fails to provide any evidence that

the instant claimed peptide is a marker for Type II diabetes, and it is not obvious what link to Type II diabetes could become evident by finding the peptide of SEQ ID NO: 1 and/or SEQ ID NO: 4 in a sample, then the claimed invention is not patentable because it is not disclosed as being useful in currently available form.

There is no disagreement that "the showing of a link between a peptide and disease implies the potential for use of the peptide for diagnosis and/or therapeutics of the disease", emphasis added (p. 22 of the Brief). The disclosure of a biological role or function of the claimed peptides is not probative of lack of utility under 35 U.S.C. § 101. As stated above, the disclosure of the specific correlation between a marker and a disease is enough to satisfy the utility requirement. However, in the instant case, the specification, as originally filed presents no evidence that the instant claimed peptides of SEQ ID NO: 1 and/or SEQ ID NO: 4 are present or absent in Type II diabetes, or "differentially expressed between a Type II diabetes patient and "normal" patient". The specification only presents photographs of two gels containing raw proteins isolated from different subjects and a statement that six short peptides "related to Type II diabetes [were] found" (p. 46).

The instant claim encompasses two peptides, which are asserted to evidence a link to Type II diabetes, but the text of the instant specification is absolutely silent to specifically identify "the link". As such, finding the claimed peptides in a sample would not provide any meaningful useful information, such as diagnosis of Type II diabetes or estimation of a risk to develop Type II diabetes or any other link to the disease. Appellant submits that the claimed peptides are fragments of fibronectin and "[f]ibronectin is a key component of the extracellular matrix; functioning, through a series of binding domains, to maintain normal cell morphology

via organization of cell attachment to the extracellular matrix. Fibronectin is particularly prone to fragmentation since the regions between the binding domains are highly susceptible to proteolysis" (p.23 of the Brief). However, in the instant case, the peptides of SEQ ID NO: 1 and 4 have never been found as naturally occurring fragments specifically associated with Type II diabetes. Moreover, to accept Appellant's working hypothesis that fibronectin molecule undergoes specific fragmentation during Type II diabetes pathology, one would reasonably expect the claimed fragments to be present not absent in Type II diabetes samples, as appears to be the case with results shown in Figures 1 and 3 (see also Declaration of F. Lander at p. 2 (a)).

Furthermore, the instant claimed peptides are considered to be fragments of a fibronectin precursor protein molecule only in so far as they share structural similarity with fibronectin (common fifteen or nineteen amino acids); however, the instant peptides could be fragments of a different naturally occurring human protein molecule. Since the art or the instant specification fail to disclose fibronectin precursor molecule as a marker for Type II diabetes, there appears to be little significance that a peptide, which shows limited structural similarity to fibronectin precursor protein, can be recognized as a marker for Type II diabetes solely based on their structural identity.

In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court specifically stated that "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion". The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. In the instant case the claimed peptides

of SEQ ID NO: 1 and SEQ ID NO: 4 are only useful for further research to establish their specific and substantial utility.

To grant Appellant a patent encompassing isolated fragments of a naturally occurring human protein, which are not readily usable in current form, would be to grant Appellant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966). To grant Appellant a patent on the claimed peptides based solely upon an assertion that the proteins are linked to Type II diabetes is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted.

Thus, since the instant specification does not disclose a credible "real world" use for the isolated fragments of SEQ ID NO: 1 and SEQ ID NO: 4 in currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

B. *Claim Rejections - 35 USC § 112, first paragraph*

Since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,

Olga N. Chernyshev, Ph.D.

Primary Examiner

OLGA N. CHERNYSHEV, PH.D.
PRIMARY EXAMINER

Conferees:

Janet Andres, Ph.D.

Supervisory Patent Examiner, AU 1649

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER

Gary Nickol, Ph.D.

Supervisory Patent Examiner, AU 1646

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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